



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/223,957	12/31/1998	RODERIC M. K. DALE	OLIG-0004	4286

9629 7590 07/02/2003

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 07/02/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/223,957

Applicant(s)

DALE ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Respons to Argum nts

The following is in response to the amendment filed 4/17/03:

An action on the merits of claims 1,3, 4 and 6-16 and 18-21 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections 35 USC § 103

Applicant's arguments filed 4-17-03 have been fully considered but they are not persuasive. The rejection of claims 1, 3-4 and 6-21 under 35 U.S.C. § 103(a) as being unpatentable over Colpan et al. (Colpan), U.S. 5,747,663 in combination with Su, U.S. 5,804,684 is maintained for the reasons of record.

Claims 1, 3, 4, 6-15 and 18-21 are drawn to a method of desalting and concentrating a nucleic acid within a sample comprising anion exchange purification with subsequent purification with a strongly hydrophobic base matrix selected from the group consisting of polystyrene, polyethylene, polyvinyl and polypropylene.

Claim 16 is drawn to the method of claim 1 wherein the linkages of the nucleic acid are 3'-5' or 5'-2' and the sample is the product of either strong or weak anion exchange chromatography.

Colpan teaches a method of purifying nucleic acids using a first step of anion exchange chromatography (col. 3, lines 40-50) with a subsequent purification using an inorganic materials such as polystyrene resins and copolymers thereof (col. 3, lines 23-67). Colpan further teaches that samples that are suitable for purification include nucleic acids such as RNA, YACs and genomic DNA obtained from cells, cell organelles, tissues or microorganisms (col.3, lines 65-67), which encompasses the claimed nucleic acid substrates (in either 3'-5' or 5'-2' forms) as well as the biological source.

While Colpan teaches the use of polymers such as polystyrene for the second purification step, it does not teach the use of the additionally claimed polymers such as polyethylene, polyvinyl and polypropylene.

Art Unit: 1623

Su bridges the nexus between the prior art and the invention as claimed as it teaches that modified hydrophobic polymers such as polyethylene, polyvinyl and polypropylene are used in the purification of nucleic acids from biological samples (col.7, lines 40-54). Su teaches that these polymers are used in nucleic acid purification because digested proteins and salts do not bind to the polymeric matrix thus they are separated from the nucleic acid. Su also teaches that the binding of the nucleic acid is reversible since the binding is not through physical trapping, affinity binding or electrostatic interactions (col. 7, lines 3-17). One of skill in the art would recognize that this form of reversible binding would be conducive to easy removal of the nucleic acid through multiple aqueous washings.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use anion exchange chromatography and a hydrophobic polymer for desalting and purification of a nucleic acid sample.

A person of ordinary skill in the art would have been motivated to use anion exchange chromatography and a hydrophobic polymeric matrix such as polyethylene, polyvinyl, and polystyrene given the art recognized benefits of reversible binding of the nucleic acid sample while allowing contaminants such as digested proteins and salts to be removed.

Applicant argues that the definition of oligonucleotides as set forth in the specification is not taught in the prior art; however, the teachings of Colpan encompass oligonucleotides and are not limited to a particular size given that Colpan distinguishes nucleic acids such as RNA, YAC's... and genomic DNA obtained from cells using anion exchange chromatography which accomplishes the initial step of desalting and concentrating the oligonucleotides which are a part of either RNA or DNA samples. Moreover, Su teaches that the nucleic acids/oligonucleotides may be of any size including that which meets applicant's definition of oligonucleotide (col. 4, lines 45-63).

Applicant further argues that the recitation of unbuffered aqueous solution as the rinsing medium is not set forth in the prior art; however, Su teaches that the nucleic acid may be recovered in water or low salt buffer (column 6, lines 65-67), thus the prior art has not excluded the use of an unbuffered aqueous medium as the rinsing agent.

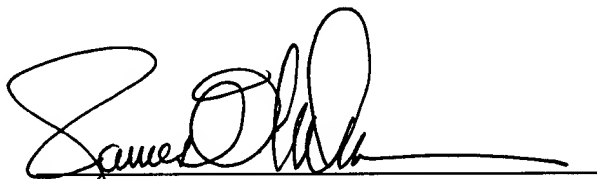
Art Unit: 1623

For the reasons cited above the 35 U.S.C. 103 rejection of record is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.